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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,945	08/04/2003	Michael S. Tyndall	KOM 4295	5207

321 7590 05/05/2006

SENNIGER POWERS
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER	
TONGUE, LAKIA J	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/633,945	TYNDALL ET AL.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-29 and 36-62* is/are pending in the application.

4a) Of the above claim(s) *12-16 and 36-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7-11, 17-29 and 52-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on February 6, 2006 is acknowledged. Claims 1, 3-5, 7-29 and newly added claims 52-62 are pending and under consideration. Claims 12-16 and 36-51 have been withdrawn from consideration. Claims 2, 6 and 30-35 have been canceled.

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Rejections/Objections Withdrawn

1. In view of applicants' response the objection to the specification on page 4 is withdrawn.

2. In view of applicants' response the rejection under 35 U.S.C 112, second paragraph on page 6, paragraph 5 is withdrawn.

3. In view of applicants' response the rejection of claims 1 and 3 under 35 U.S.C. 102(b) as being anticipated by Beerse et al (US 6,258,368 B1) on page 7, paragraph 6 is withdrawn.

4. In view of applicants' response the rejection of claims 1-4, 17, 28, 29 and 30 under 35 U.S.C. 102(b) as being anticipated by Khan et al (US 5,824,359) on page 8, paragraph 7 is withdrawn.

5. In view of applicants' response the rejection of claims 1,3, 7, 17, 24, 28 and 29 under 35 U.S.C. 102(b) as being anticipated by Jampani et al (WO 01/41727 A1) on page 10, paragraph 8 is withdrawn.

6. In view of applicants' response the rejection of claims 1, 17, 24 and 28 under 35 U.S.C. 102(e) as being anticipated by Mayne et al (US 6,881,427 B2) on page 11, paragraph 9.

7. In view of applicants' response the rejection of claims 1,2,30 and 32-35 under 35 U.S.C. 102(e) as being anticipated by Hei et al (US 6,436,445 B1) on page 12, paragraph 10 is withdrawn.

Rejections/Objections Maintained

8. The rejection of claims 1, 3-5, 7-11, 17-29 and newly added claims 52-62 under 35 U.S.C. 112, first paragraph is maintained for the reasons set forth in the previous office action on page 4, paragraph 4.

The rejection was on the grounds that while being enabling for a composition for treating bovine mastitis comprising a phospholipd-containing skin conditioner and an antimicrobial agent, does not reasonably provide enablement for a composition for the treatment or prevention of any infection in any and all animals. The specification does

not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant urges that claim 1 has been amended and is limited to a topical veterinary composition for the treatment or prevention of bovine mammary infections, and more specifically in new dependent claim 52, to the treatment or prevention of mastitis.

It is the examiners position that while applicant has provided enablement for the treatment of bovine mastitis by administering a composition comprising iodine and a phospholipid, applicant has not shown any evidentiary data to provide enablement for a composition for the prevention of bovine mastitis or any bovine mammary infection as set forth in claim 1.

The state of the art is one that discloses that prevention is key to controlling mastitis. Mastitis control based solely on antibiotic therapy during lactation is both costly and ineffective. Moreover, prevention is based on reducing the number of bacteria to which the teat end is exposed. The basic management procedures which have been shown to have the greatest effectiveness in preventing mastitis are a) teat dipping and dry cow therapy, b) milking time hygiene, c) predipping, d) culling, e) segregation, f) lactational therapy of clinical mastitis and g) vaccines (Harmon et al (Controlling Contagious Mastitis, http://www.nmconline.org/articles/contagious.htm, 1996, pages 2-4). Moreover, Dyer (US Patent 6,525,071 B2) discloses that while iodine is perhaps the most widely used active ingredient in such compositions, iodine damages

the udder skin. Even in once- to twice daily milking situations, iodine can have long-term negative effects on the udder skin condition (column 2, lines 33-37, 44-49).

New Grounds of Rejection

Specification

9. The disclosure and claims 1, 56 and 62 are objected to because of the following informalities: the words "stearamidopropyl", and "borageamidopropyl" are spelled incorrectly. The correct spelling is stearamideopropyl and boregeamidopropyl respectively.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 3, 4, 8, 9, 24, 28, 29, 52 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Jampani et al (U.S. Patent 6,248,343).

Independent claim 1 is directed to A topical veterinary composition for the treatment or prevention of bovine mammary infection comprising iodine as an anti-microbial agent and a phospholipld-containing skin conditioner, wherein the phospholipid is selected from the group consisting of: linoleamidopropyl

phosohatidylglycerol dimonium chloride phosphate; cocoamidopropyl phosohatidylglycerol dimonium chloride phosphate; sunfloweramidopropyl phosohatidylglycerol dimonium chloride phosphate; sodium olivamidopropyl phosohatidylglycerol dimonium chloride phosphate; stearamideopropyl phosohatidylglycerol dimonium chloride phosphate; ricinoleamidopropyl phosohatidylglycerol dimonium chloride phosphate; di-linoleamidopropyl phosohatidylglycerol dimonium chloride phosphate; poly (ethylene glycol)$_{n=8}$ dimethicone sunfloweramidopropyl phosohatidylglycerol dimonium chloride phosphate complex; dimethicone safflowerамidopropyl phosohatidylglycerol dimonium chloride phosphate complex; sodium grapeseedamidopropyl phosphatidylglycerol dimonium chloride phosphate; and sodium boregeamidopropyl phosohatidylglycerol dimonium chloride phosphate.

Jampani et al discloses topical skin care compositions that comprise antimicrobial agents (iodine) in effective amounts from about 0.1 to about 4.0 percent by weight and phospholipids from about 0.01 to about 1.0 (column 5, lines 29-42). Jampani et al discloses adding coco phosphatidyl PG-dimonium chloride (hydrophilic oil skin conditioner; Phospholipid CDM, Uniquema) from about 0.01 to about 1.0 percent by weight (column 5, lines 40-43). Moreover, Jampani et al discloses adding a mixture of anionic or a nonionic surfactant, using from about 0.05% to about 5% by weight of the surfactant. Jampani et al discloses that the alkyl group has from 8 to 18 carbon atoms. Additionally, suitable nonionic agents have alkyl groups from about 7 to 18 carbon atoms, such as lauric acid, myristic acid, palmitic acid, oleic acid and the like (column 8,

lines 33-53). Jampani et al discloses the use of thickening agents (column 6, line 60). Lastly, Jampani et al discloses adding tocopheryl acetate and vitamin E to the compositions (column 14, line 45).

Claim limitations such as "for the treatment or prevention of bovine mammary infections " and "wherein the bovine mammary infection is mastitis" are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey,* 152 USPQ 235 (CCPA 1967) and *In re Otto,* 136 USPQ 458, 458.

11. Claims 1, 7, 28, 29, 52 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al (US 2002/0086039 A1).

Independent claim 1 is directed to A topical veterinary composition for the treatment or prevention of bovine mammary infection comprising iodine as an anti-microbial agent and a phospholipld-containing skin conditioner, wherein the phospholipid is selected from the group consisting of: linoleamidopropyl phosohatidylglycerol dimonium chloride phosphate; cocoamidopropyl phosohatidylglycerol dimonium chloride phosphate; sunfloweramidopropyl phosohatidylglycerol dimonium chloride phosphate; sodium olivamidopropyl

phosohatidylglycerol dimonium chloride phosphate; stearamideopropyl phosohatidylglycerol dimonium chloride phosphate; ricinoleamidopropyl phosohatidylglycerol dimonium chloride phosphate; di-linoleamidopropyl phosohatidylglycerol dimonium chloride phosphate; poly (ethylene glycol)$_{n=8}$ dimethicone sunfloweramidopropyl phosohatidylglycerol dimonium chloride phosphate complex; dimethicone safflowerамidopropyl phosohatidylglycerol dimonium chloride phosphate complex; sodium grapeseedamidopropyl phosphatidylglycerol dimonium chloride phosphate; and sodium boregeamidopropyl phosohatidylglycerol dimonium chloride phosphate.

Lee et al discloses topical compositions (i.e. creams and lotions) which comprises iodine and linoleamidopropyl phosohatidylglycerol dimonium chloride phosphate (0044, 0213 and 0234). Moreover, Lee et al discloses that cocoamidopropyl phosohatidylglycerol dimonium chloride phosphate and tocopherol acetate can be added to the compositions (0113).

Claim limitations such as "for the treatment or prevention of bovine mammary infections " and "wherein the bovine mammary infection is mastitis" are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference

as compared to the art. See *In re Casey,* 152 USPQ 235 (CCPA 1967) and *In re Otto,* 136 USPQ 458, 458.

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

12. No claims are allowed.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jampani et al (U.S. Patent 6,022,551).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LJT
4/13/06

NITA MINNIFIELD
PRIMARY EXAMINER